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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,464	07/26/2004	Carmen V. Sciortino Jr	US 1396/04 (VA)	4010

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,464	SCIORTINO JR, CARMEN V.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/28/06, 7/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending. Claims 1-13 have been withdrawn as being drawn to non-elected inventions. Claims 14-18 are currently under examination.

Election/Restrictions

Applicant's election, with traverse, of Group III in the response filed 4/28/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The use of the trademark Trizma has been noted on page 12 in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It should be noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of trademarks.

Information Disclosure Statement

The information disclosure statements filed on 7/23/2004 and 4/28/2006 have been considered. Initialed copies are enclosed. Document EP 0338395 B1/A3 (page 1, IDS filed 4/28/2006) has not been considered, as no translation was available. The references from Bivda (page 5, IDS filed 4/28/2006), Commonwealth Biotechnologies (page 5, IDS filed 4/28/2006), Iglewski (page 5, IDS filed 4/28/2006), Sciortino (Hybridoma, 12:333-342, page 6, IDS filed 4/28/2006), and US FDA (page 7, IDS filed 4/28/2006), have not been considered, as not copies have been provided. Said references will be considered as they become available.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to kits containing, in part, an antibody specific for a lipoprotein of *Pseudomonas aeruginosa.*

The claims are drawn to a vast genus of antibodies which can bind any lipoprotein of *Pseudomonas aeruginosa.* To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of antibodies which can bind any lipoprotein of *Pseudomonas aeruginosa*, Applicant must adequately describe the antigenic determinants (immunoepitopes) to which said antibodies would bind.

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus of antibodies to which the claims are drawn, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of antibodies. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to

adequately describe at least a substantial number of members of the genus of antibodies to which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of antibodies which can bind any lipoprotein of *Pseudomonas aeruginosa*.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant

shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can bind to a given antibody can only be identified empirically. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of antibodies which can bind to a given lipoprotein of *Pseudomonas aeruginosa*. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of antibodies to which the claims refer. Hence, the claims do not meet the written description requirements. Regarding claim 17, where the monoclonal antibody is PS2, the designation of PS2 constitutes a laboratory designation that does not provide any structural or functional limitation, nor does it provide a description of such an antibody.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the monoclonal antibody designated PS2 is required in order to practice the invention. Specifically, it is noted that claim 17 recites deposited material. The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CRF 1.808(a)).

If the deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit, or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; and

3) the deposits will be maintained for a term of at least thirty (30) years from the date of the deposit or for the enforceable life of the patent or for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited material, whichever is longest; and

4) a viability statement in accordance with the provisions of 37 CFR 1.807; and

5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CRF 1.809(d) should be added to the specification. See 37 CFR 1.803 - 1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rendered vague and indefinite by the phrase "monoclonal antibody PS2." It is not clear what antibody applicant is referring to. The name "PS2" constitutes a laboratory designation that does not impart some functional or structural definition to the antibody.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ansorg *et al.* (J. Clin. Microbiol., 20:84-88, 1984).

The instant claim is drawn to a kit for testing for the presence of *Pseudomonas aeruginosa*, comprising an agglutination reagent and an antibody specific for a lipoprotein of *Pseudomonas aeruginosa.*

Ansorg *et al.* disclose a method of testing for the presence of *Pseudomonas aeruginosa* using a coagglutination test (see abstract). Ansorg *et al.* disclose an agglutination reagent (*Staphylococcus aureus*) and monoclonal antibodies specific for *Pseudomonas aeruginosa* H antigens (see page 84-85, methods section). *Pseudomonas aeruginosa* H antigens are lipoproteins, as evidenced by Stanislavsky *et al.* (FEMS Microbiol. Rev., 21:243-277, 1997, see table 8 and page 264, column 2, paragraph 2) and Hancock *et al.* (J. Bacteriol., 145:628-631, 1981, see table 1).

Ansorg *et al.* differs from the instant application in that the reagents required for the coagglutination test are not disclosed specifically as a kit.

However, it would have been obvious to one of skill in the art, at the time of invention, to bundle the reagents needed in a kit because it is standard to put necessary reagents together in a useful form for ease of use.

Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ansorg *et al.* (J. Clin. Microbiol., 20:84-88, 1984) in view of Sciortino (Hybridoma, 12:327-332, 1993, IDS filed 7/23/2004).

The instant claims are drawn to a kit for testing the presence of *Pseudomonas aeruginosa* in a sample, comprising: a) an agglutination reagent and b) an antibody specific for a lipoprotein of *Pseudomonas aeruginosa* (claim 14). Further limitations include the kit of claim 14, further comprising a reagent for extracting the lipoprotein from *Pseudomonas aeruginosa* (claim 15); the kit of claim 15, wherein the agglutination reagent comprises a strain of *Staphylococcus* bacteria (claim 16); the kit of claim 16, wherein the antibody comprises monoclonal antibody PS2 (claim 17); and the kit of claim 15, further comprising a negative control reagent (claim 18).

Ansorg *et al.* disclose a method of testing for the presence of *Pseudomonas aeruginosa* using a coagglutination test (see abstract). Ansorg *et al.* disclose an agglutination reagent (*Staphylococcus aureus*), negative control reagent, and monoclonal antibodies specific for *Pseudomonas aeruginosa* H antigens (see page 84-85, methods section). *Pseudomonas aeruginosa* H antigens are lipoproteins as evidenced by Stanislavsky *et al.* (FEMS Microbiol. Rev., 21:243-277, 1997, see table 8 and page 264, column 2, paragraph 2) and Hancock *et al.* (J. Bacteriol., 145:628-631, 1981, see table 1).

Ansorg *et al.* differs from the instant application in that the reagents required for the coagglutination test are not disclosed specifically as a kit. Ansorg *et al.* also differs from the instant application in that they do not disclose a reagent for extracting the lipoprotein from *Pseudomonas aeruginosa* or that the monoclonal antibody is PS2.

Sciortino discloses a monoclonal antibody called PS2 which is specific for lipoprotein I of *Pseudomonas aeruginosa* (see abstract). Sciortino further discloses that lipoprotein I can be separated from other membrane proteins by incubation in Triton® X-100 (see page 329, paragraphs 5-6) and that lipoprotein I is unique and common to all *Pseudomonas aeruginosa* and further confirms that lipoprotein I is ubiquitous in 99.4% of *Pseudomonas aeruginosa* strains and is rarely found in other gram-negative bacteria.

Consequently, it would have been obvious to one of skill in the art, at the time of invention, to combine the agglutination reagent (*Staphylococcus aureus*) and negative control reagent of Ansorg *et al.* with the monoclonal antibody PS2 and the reagent for extracting lipoprotein I of Sciortino into a kit, because it is standard to put necessary reagents together in a useful form for ease of use. One would have been motivated to include the monoclonal antibody PS2 and the extraction reagent because lipoprotein I (to which PS2 binds) is unique and common to all *Pseudomonas aeruginosa* and extraction of lipoprotein I using Triton® X-100 separates and purifies the antigen.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gangle whose telephone number is 571-272-1181. The examiner can normally be reached on M-F 8:00 am - 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Brian Gangle
AU 1645

ROBERT A. ZEMAN
PRIMARY EXAMINER